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10/598,698	09/08/2006	Klaus Hellerbrand	79650-341358	9077

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EXAMINER

HEYER, DENNIS

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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05/14/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/598,698	Applicant(s) HELLERBRAND ET AL.	
	Examiner DENNIS HEYER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 19-47 and 49-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/28/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1 – 50 are currently pending

Election/Restrictions

Applicants' election of group I, which reads on Claims 1 – 17 and 48, with traverse, in the reply filed on April 4, 2009 is acknowledged. In response to the requirement that Applicant elect two species for Group I, election of GDF-5 (reading on Claims 4 – 7), without traverse and the method Claim 18, with traverse, is acknowledged.

The traversal is on the ground(s) that the Examiner has not met the requirement for establishing lack of unity. Applicant argues that the invention, as recited in Claim 1, of the instant application is not anticipated by the prior art which relied on WO03/043673 (the '673 application). Applicant argues that for the method described on pages 6 and 7 of the '673 application, step c, there is no indication that the drying of the device is performed 'while the device is 'in contact with the solution'. Examiner agrees that there is no explicit mention in the '673 application of the limitation that drying be performed while the device is in contact with the solution. However, as any drying process, inherently, must remain in contact with the solution until it is dried, the prior art method may reasonably be interpreted to mean that, the device, as described in step c, remains in contact with the solution. Examiner agrees with Applicant's

Art Unit: 1615

description of the coating process as described on page 27 of the instant application, however, such limitations are representative of an embodiment and are not presented in the Claims. Accordingly, Applicant's request that Groups I, III and IV be examined together is found not to be persuasive. The requirement is still deemed proper and is therefore made FINAL.

Finally, regarding Applicant's request that Claim 18 be examined together with Claim 1 – 17 and 48 of Group I, upon reconsideration, Claim 18, which depends from Claim 1, will be rejoined with Group I.

Claims 1 – 18 and 48 are pending in the instant office action.

Priority

This application 10598698, filed 09/08/2006 is a national stage entry of PCT/EP05/02506, International Filing Date: 03/09/2005 and claims the benefit of foreign priority to EP04005708.5, filed 03/10/2004.

Claim rejections – 35 USC § 112 – 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 48 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1615

Use claim terminology is used with and in conjunction with process and steps of processes. Use claim terminology for method, composition and comprising terminology is not acceptable (MPEP 2173.05)

Applicant is required to provide a clarification of these matters or correlation with art-accepted terminology so that a proper comparison with the prior art can be made. Applicant should be careful not to introduce any new matter into the disclosure (i.e., matter which is not supported by the disclosure as originally filed).

Claim rejections – 35 USC § 101

The following is a quotation of the first paragraph of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 48 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 48 is directed to 'use of a method of coating a device' but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. [emphasis added].

Instant claim 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for drying a solution, does not appear to be enabled for the method of removing volatile components after drying. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention (removing volatile components after step b in instant Claim 1). It is unclear how a drying step can be accomplished after the step of drying. This is a Scope of Enablement Rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561-1562, 27 USPQ2d 1510, 1513 (Fed.Cir.1993). Explaining what is meant by “undue experimentation”, the Federal Circuit has stated that:

The test is not merely quantitative since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance, with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPGv.Guardian, 75 F.3d 1558, 1564 (Fed.Cir.1996).

Art Unit: 1615

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Exparte Forman*, 230 USPQ 546 (Bd. Apls. 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108,427 F.2d 833,839, 166 USPQ 18, 24 (1970). Keeping that in mind, the *Wands* factors are relevant to the instant fact situation for the following reasons:

The *Wands* factors have all been considered. As the nature of the invention, the act of performing a drying step after a drying step has already been performed, is unclear, it would be unpredictable as to how one would carry out such a step. Regarding the state of the art, as it is unclear how such a process may be carried out the relative skill of one in the art to do so would necessarily be very high. There are no working examples provided in the specification.

Art Unit: 1615

This is undue experimentation given the limited guidance and direction provided by Applicants.

Accordingly, the instant claims do not comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success

Claim rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent

(e) the invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language

Instant Claims 1 – 5 and 8, 12, 14 and 16 – 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Song in WO 2005/016399 A1 (filing date: August 11, 2004, published: February 24, 2005).

Regarding instant Claim 1, the reference teaches a method for contacting a solution comprising a therapeutic agent and an antioxidant with a medical

Art Unit: 1615

device substrate and removing the solvent from the solution to form the therapeutic-agent—containing region (Abstract, steps c and d). The reference does not use the phrase "drying said device while being in contact with said solution" as recited in step b of instant Claim 1, however, it is inherent in any drying process that the material being dried is *in contact with* a solvent or other volatile material throughout the drying process.

Regarding instant Claim 2, the reference teaches (page 13, Example 3, section [0051]) that the solvent, tetrahydrofuran, a volatile material, is removed by drying in a preheated oven. Absent evidence to the contrary, it is presumed that the cited drying step is carried out for the purpose of removing all volatile components

Regarding instant Claim 3, the removal of volatiles (solvent THF) is performed simultaneously with removal of solvent as the only apparent volatile is, in fact, the solvent (page 13, Example 3, section [0051]).

Regarding instant Claim 4, the reference teaches that the solution contacting the medical device substrate comprises a therapeutic agent (Abstract, step a (ii)).

Regarding instant Claim 5, the reference teaches that exemplary therapeutic agents include small molecules such as retinoic acid and rapamycin (page 5, section [0030], page 13, Example 3, see also Claims 13 and 14).

Regarding instant Claim 8, the reference teaches that the solution contacting the medical device comprises non-active ingredients, specifically, a

Art Unit: 1615

polystyrene-polyisobutylene block copolymer (page 13, Example 3, paragraph [0050]).

Regarding instant Claim 12, the solution contacting the medical device is an organic solvent, tetrahydrofuran (page 13, Example 3, paragraph [0050]).

Regarding instant Claim 14, wherein the solution contacting the medical device contains an antioxidant, the reference teaches that the solution contacting the medical device may comprise an antioxidant, such as BHT or tocopherol (Abstract, step a (iii), see also, page 13, Example 3, paragraph [0050]).

Regarding instant Claims 17 and 16, the reference teaches that the medical device may be a stent (page 13, Example 3, paragraph [0050]) and that the medical device includes any coated substrate which can comprise, for example, metal (page 3 - 4, paragraph [0020]).

Claim rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Art Unit: 1615

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Instant Claims 1 – 5 and 8, 11 - 12, 14 and 16 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 (filing date: August 11, 2004, published: February 24, 2005) in view of www.science.unitn.it/~gcsmf/facilities/dip-coating.htm (the 'dip coating method reference', published: October 22, 2004)

As noted in the 102(e) rejection above, the Song reference teaches a method for coating a medical device comprising the steps of contacting a solution comprising a therapeutic agent and an antioxidant with a medical device substrate and removing the solvent from the solution. The solution contacting the medical device is an organic solvent (tetrahydrofuran) that comprises an antioxidant (such as BHT or tocopherol), a therapeutic agent (*trans*-retinoic acid) and a non-active ingredient (such as, a polystyrene-polyisobutylene block copolymer).

The reference does not explicitly teach the method step limitation of instant Claim 11. Instant Claim 11 requires that the coating and drying steps of instant Claim 1 be performed within the device's packaging container. As noted above, the Song reference does not provide an explicit teaching of the limitations

Art Unit: 1615

of instant Claim 11 but does teach that the coating method of instant Claim 1 may be carried out by dipping techniques (page 11, paragraph [0042]).

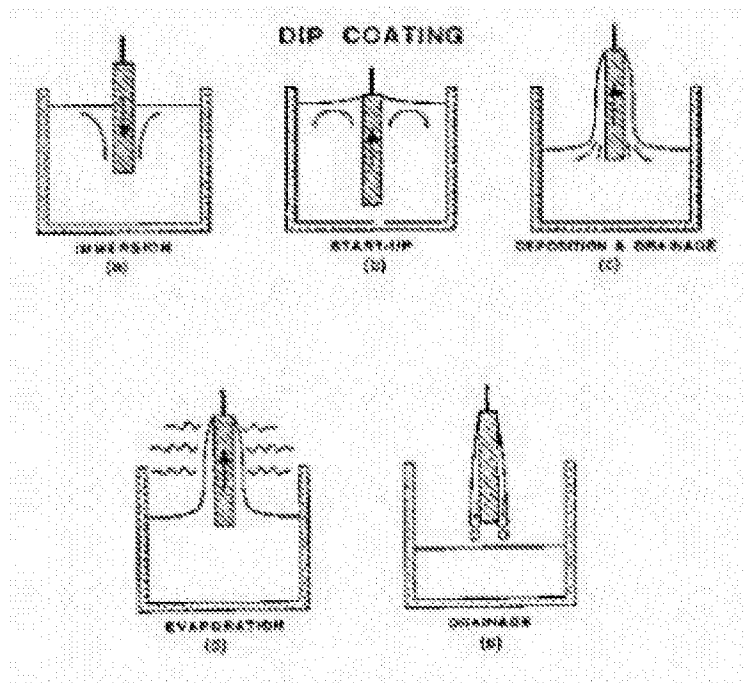


Figure 1: Stages of the dip-coating process.

As illustrated above, 'dip coating method reference' (Figure 1) shows that the dip coating process comprises the steps of immersing a substrate (such as a medical device) into a container (which may be a packaging container) and evaporation of the solvent (and all volatiles) while the substrate is within (or 'received') its container. Thus, it would have been prima facie obvious to one of ordinary skill in the art, at the time the invention was made, to have envisaged practicing the well-recognized process of dip-coating to arrive at the limitations of instant Claim 11.

Regarding instant Claim 18, drawn to further limitations of step (a) of instant Claim 1, wherein the device is inserted into a container filled with a

Art Unit: 1615

coating solution, Figure 1, clearly illustrates these limitations. Note that during the 'evaporation' step (d) the device remains in contact with the coating solution throughout any subsequent drying process.

The motivation to combine the method steps taught by Song with the dip-coating process is provided by Song who teaches that it may be beneficial to maintain a therapeutic agent coated onto a medical device in a non-oxidizing environment (page 12, paragraph [0046] and [0047]). Placing such a device and the contacting solution into a package in order to minimize exposure of the subsequently coated device to oxidants would provide additional stability to a readily oxidized therapeutic agent (such as trans-retinoic acid, see page 12, paragraph [0049]). Thus adapting the art-recognized practice of the dip-coating method for the purpose of limiting oxidation of sensitive therapeutic agents would be expected to provide benefit with a high expectation of success.

Instant Claims 1 – 14, 16 – 18 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 (filing date: August 11, 2004, published: February 24, 2005) and the 'dip coating method reference' (published: October 22, 2004) as applied to Claims 1 – 5 and 8, 11 - 12, 14 and 16 – 17 above, and further in view of Kohnert *et al.* in WO 2003/043673 (publication date: May 30, 2003).

As noted in the 102(e) and 103(a) rejections above, the Song reference teaches a method for coating a medical device comprising the steps of contacting a solution comprising a therapeutic agent and an antioxidant with a medical device substrate and removing the solvent from the solution. The

Art Unit: 1615

solution contacting the medical device is an organic solvent (tetrahydrofuran) that comprises an antioxidant (such as BHT or tocopherol), a therapeutic agent (*trans*-retinoic acid) and a non-active ingredient (such as, a polystyrene-polyisobutylene block copolymer). The 'dip coating method reference' teaches the dip-coating method, and illustrates how this method meets the limitations of instant Claims 11 and 18.

Regarding instant Claim 6, drawn to the immobilization of a pharmaceutically active substance in a bioresorbable material, the Song reference teaches that the contacting solution for the medical device may comprise non-active ingredients such as the copolymer, polystyrene-polyisobutylene, as disclosed in working Example 3. The Song reference teaches that alternative non-active ingredients can include the bioresorbable polymer hyaluronic acid, but does not incorporate such polymers into a working example.

The Song reference does not teach Applicant-elected pharmaceutically-active compound, the osteoinductive protein GDF-5 (instant Claim 7) nor calcium phosphate (instant Claim 9). The Song reference also does not teach an aqueous contacting solution (instant Claim 13), a drying step comprising isothermal drying (instant Claim 10) nor does the Song reference teach that the method of instant Claim 1 improves the homogeneous distribution of the coating on the device (instant Claim 48).

Kohnert teaches devices having osteoconductive and osteoinductive properties. Kohnert teaches a method for preparing said devices comprising

Art Unit: 1615

providing a solution comprising an osteoinductive protein and a buffer and contacting the solution with a carrier containing calcium phosphate. The Kohnert reference also teaches the step of drying the coated carrier (page 6, paragraph 3 to page 7, paragraph 1).

Regarding instant Claims 4, 5 and 7 drawn to a pharmaceutically active substance within the contacting solution of instant Claim 1, Kohnert teaches a preferred substance is a protein, Applicant-elected specie GDF-5 (see Claim 16).

Regarding instant Claim 6 and 9, Kohnert teaches that the contacting solution comprises carrier containing calcium phosphate (page 6, 3rd paragraph).

Regarding instant Claim 13, Kohnert teaches that the contacting solution comprises a buffer, and that, preferably, the preferred pH is between 4 and 6 (page 8, paragraphs 3 and 4), which meets the limitation of the instant Claim that the contacting solution be an aqueous acidic solution.

Regarding instant Claim 48, drawn to a homogeneous distribution of the coating on the device. Note that this Claim has been rejected under U.S.C. 101 and 112 2nd paragraph as being directed to a nonstatutory class (a “use” claim). The claim is being examined with respect to the prior art by being interpreted as a product Claim. Accordingly, Kohnert teaches a method that provides a homogeneous coating on the surface of the device (page 6, paragraph 3 to page 7 paragraph 1, in particular step (c)) and teaches that an advantage of the present invention is the homogeneous coating which is achieved during the coating process (page 7, paragraph 4).

Art Unit: 1615

Regarding instant Claim 10, drawn to the drying step comprising isothermal drying, the term isothermal drying is defined on page 20, lines 7 – 25 of the instant specification to include freeze-drying and vacuum-drying. Kohnert teaches that the drying step, preferably, is achieved by vacuum or freeze-drying (page 7, 2nd paragraph).

The motivation to apply the teachings of Kohnert to the method of coating a device, is the explicit teachings of Kohnert that acid aqueous solutions (preferably pH 4-6) prevent the precipitation of the protein, Applicant-elected GDF-5, from solution and insures that the device achieve a homogeneous coating (page 7, paragraph 3 and 4) as nonhomogeneous coatings can lead to decreased osteoinductive properties (page 6, 2nd paragraph). The motivation to combine a bioresorbable material such as calcium phosphate with the teachings of Song is that calcium phosphates, as taught by Kohnert, are effective bone-replacement materials (Page 1, paragraph 2). The motivation to combine the teachings of Song with the osteoinductive protein GDF-5, in immobilized form (in a calcium phosphate matrix) as taught by Kohnert is the teaching by Kohnert that such protein osteogenic factors exert their effect only in an immobilized form (page 2, paragraph 2). The motivation to employ an isothermal drying method is the well-recognized advantage of freeze-drying proteins that may be sensitive to higher temperatures.

Thus it would have been *prima facie* obvious to one of ordinary skill in the art, to apply the method of Song (with an antioxidant) with the dip-coating method, and the teachings of Kohnert (inclusion of GDF-5 immobilized in calcium

Art Unit: 1615

phosphate), at the time the invention was made, to arrive at the claimed invention with a predictable and reasonable expectation of success.

Instant Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 (filing date: August 11, 2004, published: February 24, 2005), the 'dip coating method reference' (published: October 22, 2004) and Kohnert *et al.* in WO 2003/043673 (publication date: May 30, 2003) as applied to Claims 1 – 14, 16 – 18 and 48 above, and further in view of Lee *et al.* in US patent 5,571,523; published November 5, 1996)

As noted in the 102(e) and 103(a) rejections above, the Song reference teaches a method for coating a medical device comprising the steps of contacting a solution comprising a therapeutic agent and an antioxidant with a medical device substrate and removing the solvent from the solution. The solution contacting the medical device is an organic solvent (tetrahydrofuran) that comprises an antioxidant (such as BHT or tocopherol), a therapeutic agent (*trans*-retinoic acid) and a non-active ingredient (such as, a polystyrene-polyisobutylene block copolymer). The 'dip coating method reference' teaches the dip-coating method, and illustrates how this method meets the limitations of instant Claims 11 and 18. The Kohnert reference teaches a method for contacting a device with a solution comprising applicant-elected specie GDF-5 and calcium phosphate. The reference teaches that the contacting solution is an aqueous acidic buffer and the limitation that the method provides a homogeneous coating of the device. The Kohnert reference also teaches

Art Unit: 1615

isothermal drying (as freeze or vacuum drying) for the method of drying the device.

As noted above the Song reference teaches an antioxidant as a component of the contacting solution of instant Claim 1, however neither of the above references specifically teach methionine as the antioxidant.

Regarding instant Claim 15, Lee *et al.* teaches a method for inhibiting arteriosclerosis by contacting an artery with an apoptosis-inducing amount of an antioxidant (Abstract). Lee further teaches that methionine is a preferred antioxidant (column 1, lines 37 – 43, Claim 7). Thus, absent evidence to the contrary, it would have been *prima facie* obvious to one skilled in the art, at the time the invention was made, based on the teachings of Song and Lee, that multiple antioxidants are recognized in the medical device art and to substitute one art-recognized antioxidant, such as BHT (taught by Song) for another, methionine (taught by Lee), would provide a predictable result (see MPEP 2143 (B)).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Thursday 8AM-5PM EST.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached at (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DH

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615